Community meetings for emergency research community consultation*

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Objective: **To survey attendees at community meetings for an emergency research protocol and determine whether these meetings aid participants' understanding and decision to support the proposed emergency research.**

Design: **Postmeeting questionnaire.**

Setting: **Three community meetings for the PolyHeme study in San Antonio area.**

Subjects: **One hundred fifty community meeting attendees.**

Interventions: **PolyHeme research team representatives made a study presentation concerning exception to informed consent regulations. In addition, institutional review board (IRB) members attended these meetings and made a separate presentation about the IRB approval of research and the exception to informed consent in emergency research. The IRB members requested attendees to voluntarily complete an additional Community Consultation Survey assessing demographics, community meeting satisfaction, and impact of the community meeting on their attitudes toward emergency research studies.**

Measurements and Main Results: **Feedback to the PolyHeme investigators with their validation questions indicated that 35% of the respondents objected to research without prior consent, but 82% gave approval for the study in the local community; 137 attendees completed the additional Community Consultation Survey. The average score on the adequacy of information provided about the PolyHeme study was 0.58 on a 5-point Likert scale (−2 to +2). Adequacy of IRB background information on human subjects research received an average score of 0.56, and the overall clarity of the information on community consultation was 0.91. Although 80% of respondents felt there was a potential benefit from PolyHeme, <67% would either want to participate or enroll their family members with or without prior consent.**

Conclusions: **The majority of community meeting attendees understand basic concepts and regulations of emergency research without prior consent. Despite an 82% concurrence with the study in their community, approximately 30% of persons would not willingly choose to participate in emergency research or provide consent for their family members despite knowledge about the process. (Crit Care Med 2008; 36:731–736)**

KEY WORDS: community meetings; emergency research protocol; PolyHeme study

In 1996, the U.S. Federal Government published the Emergency Research Consent Waiver, which permitted local institutional review boards (IRBs) to grant an exception to informed consent requirements where specific conditions were met (1). The basic requirements for this type of emergency research provision are the following: 1) Participants are in a life-threatening situation where available treatments are unproven or unsatisfactory; 2) obtaining informed consent in advance is not feasible; 3) there is potential for direct benefit to the participant; and 4) the research could not be practically carried out without a waiver. The final stipulation of this regulation is that certain requirements must be met in the community where the research is to be conducted. This condition requires 1) consultation with representatives of the communities in which the research will be conducted; 2) public disclosure to the communities before initiation of the research; and 3) public disclosure of the research findings to apprise the community of the results of the study (1).

There is no specific stipulation in the emergency research consent exception as to how public disclosure to the communities before conduct of the research study must be done. The 1998 guidance from the Food and Drug Administration (FDA) recommends the following: "The agency expects the IRB to provide an opportunity for the community from which research subjects may be drawn to understand the proposed clinical investigation and its risks and benefits and to discuss the investigation . . . IRBs should consider, for example, having a public meeting in the community to discuss the protocol" (2). The public meeting was one of several acceptable methods to provide the IRB with community input for its final decision-

*See also p. 993.

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making process to approve emergency research. The current FDA draft guidance from July 2006 is more specific in its intent and encourages a broader role of the IRB in the community consultation process. "The IRB should consider the community's opinions and concerns, and assess the adequacy of the consultation process. In addition, the IRB should incorporate the results of community consultation and discussion into the IRB's own decision-making about the protocol. For this reason, the IRB may wish to directly listen to the community discussions and concerns expressed in those discussions, and not rely solely on summary documentation by the clinical investigator or feedback reported by others" (3). The draft guidance suggests that the IRB should take the following measures: 1) review and approve plans for community consultation; 2) assess the adequacy of the community consultation; 3) consider the community concerns and incorporate the feedback into its review of the protocol; and 4) reflect consideration of community consultation in the IRB's written summary.

Numerous publications and editorials have discussed the implications and merits of the emergency research consent exception, but few specifically comment on including community meetings as a component of the community consultation process. As an early investigation into the community consultation process, Shah and Sugarman (4) used the FDA's repository of public disclosure to evaluate one-way and two-way communication from two trauma and two cardiac trials. They found that many two-way communications, such as community meetings, were not directed at lay persons, and often <15 participants were involved (4). Santora and colleagues (5) likewise provided comment on their overall approach to community consultation. Their plan included a series of four public meetings during which members of the research team made presentations about the study and the regulations governing informed consent and answered questions (5). Kremers et al. (6) reported on the use of a public forum for their cardiopulmonary resuscitation vest study and noted only 25 people attended. The authors commented effectiveness of these meetings was difficult to judge given the small numbers of participants.

The current literature lacks any conclusive data on the methods used to conduct community meetings for this purpose or the overall effectiveness of this approach. The objective of this study was to evaluate the effectiveness of these meetings in achieving the intent of the Final Rule to discern the community's opinion toward an emergency research trial. The investigators sought to discern if the demographics of community meeting attendees represented the community at large, if attendees were satisfied with the information provided, and whether the community meeting affected their willingness to participate or give consent for a family member to participate.

Table 1. PolyHeme investigator validation questionnaire

1. Do you understand what this study is about based on the presentation?	Yes	No
2. Do you understand that participants in the study will not be giving their consent before beginning and that instead your community is giving its approval of this study?	Yes	No
3. Do you object to the enrollment of someone in this research study without their individual consent before the study begins?	Yes	No
4. Would you be willing to allow us to do this study in your community?	Yes	No
5. Comments:		

Optional information: age, ethnic background, gender.

METHODS

In 2004, U.S. Army investigators submitted their proposal for community consultation as part of the review and approval process for the Northfield PolyHeme study titled "A Phase III, Randomized, Controlled, Open-Label, Multicenter, Parallel Group Study Using Provisions for Exception to Informed Consent Requirements Designed to Evaluate the Safety and Efficacy of Poly SFH-P Injection (Polymerized Human Hemoglobin [Pyridoxylated], PolyHeme) When Used to Treat Patients in Hemorrhagic Shock Following Traumatic Injuries Beginning in the Prehospital Setting." Their requested community consultation plan included a community meeting at the local Army post Fort Sam Houston, where Brooke Army Medical Center (BAMC) is located, and two community meetings in the northeast suburbs of San Antonio in the towns of Live Oak and Converse, whose civilian populations are also served by the BAMC level 1 trauma center. The PolyHeme study had already been initiated in San Antonio by the University of Texas Health Science Center at San Antonio, and community meetings had previously been held at nine other locations in the 22-county South Texas Trauma Region. The BAMC IRB approved these three additional community meetings that specifically targeted community members in the geographic regions surrounding BAMC. The authors submitted a survey research study of the community consultation meetings, which was determined to be exempt research by the BAMC IRB.

The presentation for the community meetings included information about the PolyHeme study, IRB approval of research, and the community consultation process. The planned format of the meeting included two presentations: one by an investigator from the PolyHeme study about the rationale and details of the study, and one by an IRB member about the usual IRB research approval process, the subject's usual right to informed consent, and the regulation allowing the exception from informed consent in specific emergency research studies. Both presentations were reviewed and approved by the BAMC IRB before the community meetings. A time for audience questions about the study and the exception from informed consent followed. An approved validation questionnaire was provided by the PolyHeme investigators to assess the adequacy of the meeting for IRB submission as part of the final approval process (Table 1). The investigators set a goal of 85% approval of the validation questionnaire by the community meeting attendees as part of their community consultation plan. At least two members of the BAMC IRB attended each of the scheduled community meetings with one providing the IRB presentation and others acting as observers.

This research survey of the community consultation assessed attendee demographics, satisfaction with the information provided, and attitude and potential willingness to participate in the research. This separate Community Consultation Survey was distributed to all attendees of the community meetings (Table 2) after the investigator validation questionnaires were submitted. The surveys completed by volunteers were placed in a separate box at the conclusion of the meeting and collected by research personnel.

RESULTS

A total of 188 people attended the three community meetings, and 150 people (80%) completed and submitted the validation questionnaire distributed by the PolyHeme investigators. Twenty-five attendees were present at the meeting in Live Oak, 101 persons attended the meeting at Fort Sam Houston, and 24 persons attended the meeting in Converse. Of

Table 2. Community consultation survey

Demographics
1. Gender, age, race, level of education, meeting attended.
2. Have you or a relative been involved in a trauma emergency incident?
3. How did you hear about this meeting?

Consultation satisfaction (strongly disagree [−2] to strongly agree [+2])
1. You received enough background information about research involving people.
2. You received enough information about this PolyHeme research study.
3. The information was given in a clear and understandable manner.

Impact
1. Do you feel patients benefit from standard (routine) emergency medical care?
2. Do you feel there is potential benefit from receiving the experimental blood substitute, PolyHeme?
3. After hearing the information provided today, would you be willing to participate in this research study in an emergency situation?
4. If one of your relatives is enrolled in the study discussed today and you are contacted *before* your relative is admitted to the hospital, would you consent (agree) for your relative to be in the study? This would mean your relative might receive PolyHeme blood substitute; laboratory tests and other clinical data would be obtained.
5. If one of your relatives is enrolled in the study discussed today and you are contacted *after* your relative is admitted to the hospital, would you consent (agree) for your relative to be in the study? This would involve data collection and laboratory tests only; either PolyHeme or crystalloid would have been given but no more would be given.
6. Is there a religious reason why you would not want to participate in the study?
7. Do you have any specific concerns about this study?

Table 3. Demographic information

	PolyHeme	Study Survey
No. completing (% of attendees)	150 (80)	137 (73)
Gender, %		
Male	75.7	70.2
Female	24.3	25.4
Age, yrs, %		
18–40	53.6	55.5
41–60	37.3	35.2
>60	9.1	9.4
Race, %		
White	67.7	54.9
Hispanic	14.7	12.0
African American	15.7	21.8
Other	2.0	7.5

Demographic information provided by the community meeting attendees to the PolyHeme investigators and the study investigators.

note, all three meetings were regularly scheduled meetings during which the PolyHeme study was one part of the agenda. Larger attendance at the Fort Sam Houston meeting occurred because of leader expectation for attendance. Gender, age, and ethnicity by percentage are shown in Table 3; only 73% of respondents provided this information to the PolyHeme investigators. Overall educational level was noted to be 12% of persons with a graduate degree, 21% with a bachelor's degree, 21% with an associate's degree, 37% with some college experience, and 8% with high school diploma or less.

Results of the PolyHeme investigator validation questionnaire indicated that 99% of respondents understood the study protocol (question 1) and 97% understood that participants would not give prior consent (question 2). Thirty-four percent objected to enrollment into the PolyHeme study without prior consent (question 3). However, 82% of respondents indicated they would give their approval for the PolyHeme study to be conducted in the community (question 4). Approval by site was lowest at Fort Sam Houston, where only 76% of respondents approved compared with 95% and 96% at the Live Oak and Converse sites, respectively. Many in the military audience worked in health-related fields and may have had a higher level of knowledge about research-related risks. The combined lowest approval by age (n = 56) was in the 18- to 40-yr-old group at 82%. The 41- to 60-yr-old age group (n = 40) and age ≥61 (n = 10) group gave approval at 93% and 100%, respectively.

The Community Consultation Survey was completed by 137 attendees (73% of all meeting attendees and 91% who completed the PolyHeme investigator questionnaire). The demographic information from this survey was more complete, with 93% of respondents providing their demographics. These data are shown in Table 3 and show few differences in distribution of age, gender, or ethnicity. On a 5-point Likert scale of −2 (strongly disagree) to +2 (strongly agree), the mean score on receiving adequate information presented about the IRB process was 0.56 and receiving enough information about the PolyHeme study was 0.58, but the question on overall clarity of presentation showed strong agreement with a score of 0.91. The tabulation for each location and topic is shown in Table 4. While the ratings at the Fort Sam Houston are consistently lower, the overall scores for each topic are favorable. The responses to the questions about the impact of the community meeting on each attendee's decisions to give approval to the PolyHeme study and the emergency research consent exception are shown in Table 5. While there was agreement for the benefit of routine emergency care by 88% of respondents, 20% were unsure after the presentation if PolyHeme provided a potential benefit for trauma patients. Notably, 73 of 137 (53%) respondents had some history of previous trauma experience for themselves or a family member. This did not have a negative impact, as 62% were in favor of the study, 22% were opposed, and 14% remained unsure. Only one of 137 respondents commented that religion affected his or her opinion. The overall results concerning participating or providing consent for a relative to participate in the PolyHeme study were uniform, with approximately 60% of respondents willing to participate, 20% unwilling, and 20% still unsure after the meeting was concluded.

DISCUSSION

The decision on how to perform community consultation for the emergency research exception to consent requirement remains an often debated and open-ended question for each individual IRB to consider when dealing with an emergency research protocol. Dickert and Sugarman (7) suggested that the four ethical goals of community consultation are enhanced protection, enhanced benefits, legitimacy, and shared responsibility. There are numerous opinions on how to accomplish these goals and inform the community, but there is little evidence on the best methodology. The approval rating reached 82% for conduct of the study in the community, and the IRB concurred with this as a very good approval rating and sufficient to proceed with the study. Our data suggest that despite the two-way interchange and discussion of an emergency research proto-

Table 4. Consultation satisfaction

	Research Background	PolyHeme	Clarity of Presentation
Live Oak	0.85	0.88	1.04
Fort Sam Houston	0.27	0.32	0.72
Converse	1.40	1.30	1.50
Overall	0.56	0.58	0.91

Results of satisfaction portion of survey listing mean values using a five-point Likert scale from −2 (strongly disagree) to +2 (strongly agree).

Table 5. Impact of community consultation

	Yes	No	Don't Know
1. Benefit from routine emergency care	108 (88)	4 (3)	11 (9)
2. Benefit from PolyHeme	99 (80)	3 (2)	21 (17)
3. Participation in emergency research	78 (64)	24 (20)	20 (16)
4. Consent relative prior to admission	75 (61)	25 (20)	23 (19)
5. Consent relative after admission	81 (67)	15 (12)	25 (21)
6. Religious objections	1 (1)	127 (99)	0 (0)

Overall results of Community Consultation Survey with individual respondents and percentages (in parentheses) for each question.

col in a community meeting, a significant number of persons are not in favor of such research. Nearly 20% of persons were clearly not in favor of personal or community participation, and 34% objected to the concept of enrollment without prior consent for this study. This is a lower approval rating than previously reported. Anecdotally, many elderly attendees had some difficulty understanding the concept and became confused about differences between do-not-resuscitate advance directives and the lack of informed consent in these settings. The separate presentation by an IRB member on the research approval process and the new regulation allowing the exception to informed consent appeared to add to the overall clarity of the issue for the audience as evidenced by the stronger agreement score on overall clarity of the presentations. The availability of an IRB member to answer questions about the exception to consent allowed under the new regulation may have provided a more complete education to the audience on research approval. Thus, the presence of IRB members and the IRB presentation on participant rights does add to the ethical goal of enhanced protection intended by the new regulation for both the potential subject and potential family members of subjects as evidenced by the improved clarity of understanding self-reported by attendees. The IRB is specifically directed to consider the community discussion in its review of the study for consideration of approval. Thus, the IRB prereview of both presentations and the attendance by some members of the actual community meetings contribute to the legitimacy of the IRB discussion and the shared responsibility with the community. Whether the community meeting changed premeeting notions about emergency research and assuaged the audience concerns about lack of consent is unclear.

The earliest report on the effectiveness of community meetings was by Santora and colleagues (5), who described their entire community consultation process for a study of hemorrhagic shock using a blood substitute (similar to PolyHeme). Four community meetings were advertised and held with a total of 83 persons from the community in attendance. These authors reported concerns about the blood substitute, ethnics, monetary gain, and the motivation for community involvement in the decision-making process (5). They noted that the community meetings were the main vehicle for public disclosure and found the inclusion of an IRB member to be helpful in explaining regulatory requirements. However, Kremers et al. (6) noted little public interest in community meeting attendance involving an in-hospital study using a cardiopulmonary resuscitation vest for cardiac arrest. Only 25 people attended the single community meeting for this protocol, of whom 60% had experience in health care; 100% gave approval for the protocol. Overall, the authors commented they found the entire community consultation process burdensome, time-consuming, and expensive (6). Given the time investment required for the low number of attendees, we would concur.

Baren and colleagues (8) used a different approach in their efforts to obtain community consultation in a randomized, placebo-controlled study of phenytoin prophylaxis for severe head injury. They surveyed parents of children with minor head injuries in the emergency department to determine likelihood of participation in an emergency research trial. The targeted approach gained 66% approval from parents and provided specific reasons cited for inclusion and exclusion to the IRB for review. While this approach did not sample the community as a whole, it did attempt to target the "community" of likely participants.

Scheduling community consultations as an addition to the agenda of a previously scheduled community organization as we did is an attempt to ensure that a larger, although perhaps a selected segment of the population attends. The largest audience for the previously scheduled military meeting is atypical of most civilian community meetings and reflects military expectations of attendance at meetings. However, the percentage coverage of an actual community is still exceedingly small even using previously scheduled meetings. Lack of age and demographic representation was also problematic. The largest report to date on the use of community meetings was described by Dix et al. (9) in 2004. As part of an emergency research protocol involving hypothermia as the initial management of brain trauma, the University of Mississippi IRB mandated community meetings throughout the state and stipulated an IRB member as a "community liaison." Their community meetings involved predominantly chapter meetings of civic organizations, and a total of seven meetings were conducted with the IRB community liaison in attendance. Notably, the final two meetings were held at the request of the IRB to include more of the state's minority population. A total of 137 persons attended and provided responses to seven questions about the research study and waiver of informed consent. The overall results were generally in agreement by >90% of respondents, with 92.5% willing to participate, 94.8% willing to allow a family member to participate, and 100% allowing the study to be conducted in their community. However, as in our study, a very small percentage of the community is reached by most com-

munity meetings, which significantly limits the generalizability of the findings for the community. This has led to new proposals for other methods, such as use of telephone polling techniques, to be evaluated in this context in future (10).

Recent commentary on the Northfield PolyHeme study has revisited issues surrounding the concept of community and the efficacy of community meetings. A commentary on the attempt by the Duke University IRB to hold community meetings within the urban Durham area reported poor attendance and a "rebuff" by local black community churches (11). Numerous editorials were written in response to Holloway's (11) concerns with community consultation by the Duke University IRB as part of the PolyHeme study. Notably, Dickert and Sugarman (12) provided the best analysis of the difficulty with community consultation and engaging relevant communities. They stated, "The guidelines requiring community consultation for studies utilizing an exception from the requirement for informed consent do little to specify what methods of consultation are helpful and appropriate for different kinds of groups, and almost no data exist on how different methods of consultation advance the goals that community consultation is designed to achieve. We need to collect these data if we are to accomplish these goals more efficiently." The conduct of two civilian community consultation meetings by the military medical center serving as their trauma center meets the ethical goal of legitimacy since these civilian residents as potential future trauma victims are community stake holders. A valid criticism of the community meetings held for the PolyHeme study at BAMC is that the geographic community was targeted and not the at-risk trauma community. Data from BAMC indicate that trauma victims are more likely to be young Hispanic males who do not reside in geographic proximity to the hospital. Thus, the age of the population at risk is distinctly opposite the age of those most likely to attend and participate in community meetings. We concur with other authors that considerable discussion and strategic planning are needed to determine what constitutes community and who should be consulted for these protocols (13, 14). For future trauma studies in this area, targeting some type of community activity widely attended by young Hispanic males should be considered.

This study has provided some additional data for consideration. The responsibility for the content of both talks was reviewed and approved by the IRB to ensure both accuracy and clarity. However, no pretesting validation of the survey questions was conducted. There was a general consensus among the different sites that the information on the study protocol and on regulatory issues regarding participant rights and consent was presented in a clear, understandable manner as established by the Likert scale. Addition of a brief posttest questionnaire to better assess true understanding is recommended for future similar studies. The community meetings also did meet the appropriate demographic population. Demographics from the 2000 United States Census indicated for the town of Live Oak a population consisting of 78% Caucasian, 27% Hispanic, and 8% African American and for town the of Converse a population of 69% Caucasian, 29% Hispanic, and 13% African American. The largest ethnic populations for these areas were represented, although attendees who described themselves as Hispanic were lower than expected. The Community Consultation Survey looked at their attitude and willingness to participate based on information presented. Despite an 82% overall approval given to the investigators for conducting the study, the satisfaction survey suggested there still was considerable doubt within the community. Nearly 20% of attendees expressed concern about their willingness to allow this research study to be conducted in their community.

The limitations of this survey research study include the generalizability of the findings and the survey limitations in the ability to measure in-depth understanding (vs. self-reported understanding) of this complex issue. Generalizability was affected by both the differences in demographics between the specific at-risk population for severe trauma and the population characteristics of those community members who actively participate in the civic organizations within the community, as well as the motivation and bias factors affecting both meeting attendance and survey completion.

The results presented here emphasize several key points about the role of community meetings in the process of community consultation. As pointed out by previous reports and the FDA guidance, it is difficult to target and meet with the representative community in significant numbers when planning community meetings. A very small percentage of the community is reached by most community meetings and has led to new proposals for other methods, such as use of telephone polling techniques, in the future. The PolyHeme investigators chose (with IRB approval) three regularly established public meetings to capture a demonstrative sample of the community who would primarily be served and would be potential candidates for the study. Since the military investigators were required to go through a lengthier, more extensive review process to include the Secretary of the Army for approval, they were unable to partner simultaneously with the local university investigators. However, the BAMC IRB did rely heavily on the findings and comments that came from other community meetings. As well established by previous studies, the inclusion of IRB members in the meeting to both observe and participate in regard to subject rights and consent issues helps to answer questions by the attendees and ensure the validity of the process for the entire IRB. There is clearly a divide between self-reported understanding of an emergency research protocol and federal regulations and willingness to participate in such protocols. Despite a 99% understanding and 82% approval for conduct in the community, the actual willingness of attendees to personally enroll themselves or a relative in emergency research was only 61% to 67%. Further research is needed to evaluate other methods of community consultation to reach more of the target community and to optimally contribute to the ethical goals of enhanced protection, benefit, legitimacy, and shared responsibility for research in the emergency setting.

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